Allergan Medical
PSE-B, EPFL
CH – 1015 Lausanne
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URGENT FIELD SAFETY NOTICE

Device: Easyband® Telemetric Gastric Band
Model: Version 2 and Version 3
FSN Ref and Date: FSNEasybandGen2&3, 4 August 2010
Type of Action: Special Patient Follow-up
Scope: All Lots/Serial Numbers of Easyband® Telemetric Gastric Band Version 2 and Version 3

Dear xxx

As a surgeon having implanted our Easyband® Telemetric Gastric Band Versions 2 & 3, Allergan wishes to thank-you for your continued efforts and support. Within the Instructions for Use [and study protocol and informed consent], certain risks were highlighted to you stating that there is a possibility that the band may fail making further adjustments not possible and that consequently a re-operation maybe required.

Allergan wishes to convey to you, that a higher than anticipated number of device failures have occurred. All lots of Easyband® Telemetric Gastric Band Versions 2 & 3 bands are affected by this FSN - please see attached for the complete list.

17 Version 2 devices were implanted in 15 patients across the 5 sites between October 2006 and February 2007, 2 band failures were reported and both bands have been explanted. 1 failure was detected at surgery. The other failure was detected at follow-up visit and explanted. 13 bands remain implanted. In the last 12 months, 0 band failures have been reported. Failure modes on explanted bands were as follows:

2 failures
- Wire corrosion due to an isolated cable defect (1)
- Cable disconnection (1)

38 version 3 devices were implanted in 37 patients across the 7 sites between December 2006 and March 2007, 8 band failures were reported and explanted. 30 bands remain implanted. In the last 12 months, 1 failure has been reported and band is still implanted. Failure modes on the 8 explanted bands were as follows:

8 failures
- Cable sheath perforation (1)
- Cable perforation (2)
- Coil's corrosion (5)

Allergan assesses that a failed device does not represent a significant increased risk to the patient. In the process of gaining the correct adjustment with any gastric band, the band may

be under-adjusted (potentially resulting in insufficient weight loss) or over-adjusted (potentially resulting in nausea, vomiting, reflux etc) prior to achieving the correct restriction for the individual patient. Should band adjustments be attempted but patients have persistent lack of weight loss or clinical signs such as reflux or vomiting, a failed band may be indicated. Should failure occur, you will not be able to adjust the band of the patient. Allergan would ask each physician to use best clinical judgement for the ongoing care of the patient with the decision as to whether to surgically explant the device to be made after an informed discussion between physician and patient.

Allergan must inform you that we are required to notify the Competent Authority in your country of this Field Safety Notice.

For your information, the current and earlier versions of the Easyband® Telemetric Gastric Band gastric device are no longer available for distribution or implant. It is important to note that the failure mechanisms associated with these devices cannot occur in any LAP-BAND™ product.

Please acknowledge receipt of this notification by completing and returning the attached Acknowledgement Form. If you have any concerns or questions related to this Field Safety Notice, please do not hesitate to contact [redacted] Allergan UK.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (if appropriate). Please transfer this notice to other organisations on which this action has an impact (if appropriate).

Yours sincerely,

[redacted]
Director of Global Product Support
Allergan Ltd, UK
[redacted]

Attachments:
FSN Physician Acknowledgement Form
List of Easyband® Telemetric Gastric Band Vers2&3 Serial Numbers affected by current FSN

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URGENT FIELD SAFETY NOTICE

Device: Easyband® Telemetric Gastric Band
Model: Gen0
FSN Ref and Date: FSNEasybandGen0, 4 August 2010
Type of Action: Special Patient Follow-up
Scope: All Lots/Serial Numbers of Easyband® Telemetric Gastric Band Gen0

Dear xxx

As a site participant in our Easyband Post-Market Study in Europe, Allergan wishes to thank-you for your continued efforts and support. Within the study protocol and informed consent/device Instructions for Use, certain risks were highlighted to both you and your patients [and approved by your Ethics Committee] stating that there is a possibility that the band may fail making further adjustments not possible and that consequently a re-operation maybe required.

Allergan wishes to convey to you, and via you to your [ethics committee and] Easyband® Telemetric Gastric Band Gen0 implanted patients, that during the course of the Easyband Post Market Study currently being conducted, a higher than anticipated number of device failures have been confirmed. Due to the nature of this failure, whereby it is suspected that an essential part of the Easyband® Telemetric Gastric Band Gen0 motor may be compromised, Allergan can no longer provide reasonable assurance of device performance. Corrosion of ball bearings within the fully sealed motor is thought to be the cause, which may result in the motor blocking, therefore no longer being able to respond to commands by the control unit. Should this failure occur, you will not be able to adjust the band of the patient. All lots of Easyband® Telemetric Gastric Band Gen0 bands are affected by this FSN - please see attached for the complete list.

Allergan assesses that a failed device does not represent a significant increased risk to the patient. In the process of gaining the correct adjustment with any gastric band, the band may be under-adjusted (potentially resulting in insufficient weight loss) or over-adjusted (potentially resulting in nausea, vomiting, reflux etc) prior to achieving the correct restriction for the individual patient. Should band adjustments be attempted but patients have persistent lack of weight loss or clinical signs such as reflux or vomiting, a failed band may be indicated. Allergan asks each physician to use best clinical judgement for the ongoing care of the patient with the decision as to whether to surgically explant the device to be made after an informed discussion between physician and patient.

If the decision is made to explant the device for reasons related to this device failure, Allergan will provide financial assistance to the patient to cover the following costs upon return of the device and submission of a Product Field Note:

- One pre-operation consultation with the surgeon;
- Reasonable fees for subsequent surgery for removal and replacement with an alternate gastric device or procedure as applicable; and
- One post-operation consultation with the surgeon.

Allergan must inform you that we are required to notify the Competent Authority in your country of this Field Notice [and that you will be required to notify your study Ethics Committee]. [As our

Clinical Trial Agreement is three-party with your institutional administration, we also feel there is a requirement also notify this third party.]

We ask you to please conduct an informed discussion with each of your patients regarding the increased risk of band failure, obtaining a signed copy of the suggested Notice to Patients (attached). You should document the conversation within your hospital/clinical source notes to be reviewed for confirmation by a representative of Allergan. Patients have the right to withdraw their consent from the study. Once the discussion with a patient has occurred, you should return the FSN Patient Follow-Up Form (attached) to the fax number indicated.

For your information, the current and earlier versions of the Easyband® Telemetric Gastric Band gastric device are no longer available for distribution or implant. It is important to note that the failure mechanisms associated with these devices cannot occur in any LAP-BAND™ product.

Please acknowledge receipt of this notification by completing and returning the attached Acknowledgement Form. If you have any concerns or questions related to this Field Notice, please do not hesitate to contact [redacted] Allergan UK.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (if appropriate). Please transfer this notice to other organisations on which this action has an impact (if appropriate).

Yours sincerely,

[redacted]
Director of Global Product Support
Allergan Ltd
[redacted]

Attachments:
FSN Physician Acknowledgement Form
FSN Notice to Patients
FSN Patient Follow-Up Form
List of Easyband® Telemetric Gastric Band Gen0 Serial Numbers affected by current FSN